IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of )
)
YUSUF ALI, )
RONALD A. BARNHART, and )
MOJGAN CLINE )
)
Serial No. 10/068,633 )
)
Filed February 5, 2003 )
)
For SKIN SANITIZING ANTIMICROBIAL ALCOHOLIC COMPOSITIONS )

Group Art Unit 1614

V. Kim, Examiner

**CERTIFICATE OF MAILING**

I hereby certify that the following correspondence was deposited with the United States Postal Service as first class mail, postage paid, in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 20, 2004.

Melinda A. Miller

Melinda A. Miller, Secy. to Rodney L. Skoglund

# DECLARATION OF MOJGAN CLINE UNDER 37 CFR 1.132

As a named inventor, I hereby declare that:

1. I am a resident of Copley, Ohio and am one of three named inventors of the above-captioned application.

2. My educational background includes receipt of a B.A. degree in chemistry from the University of Akron and a Ph.D. degree in chemistry from Virginia Polytechnic Institute and State University. Since completing my degrees, I have had extensive experience in the field of chemical formulations for various applications including foot care products and hand sanitizers, and all of my three (3) patents are in these fields.

3. I have been employed by GOJO Industries, Inc., Akron, Ohio, for approximately three and one half years and am presently, Formula Development Manager there. I have been developing and testing hand sanitizing formulas during my entire tenure with GOJO.

4. As a co-inventor of the above-captioned application, I have read and reviewed all of the Office Actions received and all of the responses provided in connection with this application, including the presently outstanding Office Action dated December 22, 2003.

5. I have also read and reviewed each of the cited prior art patent references used to reject the pending claims of the present application, namely Samour et al. U.S. Patent No. 5,976,566, McKenzie et al. U.S. Patent No. 5,747,021, and Sequeira et al. U.S. Patent No. 4,775,529.

6. I understand that claims 1-7, 9-10, 12 and 25 have been rejected as being anticipated by Samour et al. U.S. Patent No. 5,976,566; that claims 1-2, 4-7, 9, 12 and 25 have been rejected as being anticipated by McKenzie et al. U.S. Patent No. 5,747,021; and that claims 1, 4-7, 9 and 25 have been rejected as being anticipated by Sequerira et al. U.S. Patent No. 4,775,529. I further understand that claim 8 has been rejected over Samour et al. in view of the BF Goodrich technical disclosure.

7. With respect to Samour et al. U.S. Patent No. 5,976,566, I understand that the Examiner asserts that Samour et al. teach a topical alcoholic gel containing 55-70% ethanol, isopropanol or mixture thereof; 0-2% cellulosic thickener, and a base to adjust the pH of the formulation. Sodium hydroxide is noted to neutralize the formulation disclosed therein. Moreover, a Carbopol® carbomer is listed as a possible thickener. Accordingly, the Examiner asserts that all of the elements of the present invention are taught by the reference and that the claimed subject matter is not considered to be patentably distinct over Samour et al.

8. I respectfully disagree. First, Samour et al. is directed to formulations suitable for drug delivery through the skin using a penetration enhancer. While the patent recited the use of ethanol, a carbomer polymer, and sodium hydroxide, these ingredients are not used together in amounts and in a manner which would provide for an alcoholic gel composition.

9. As now amended, the claims of the present invention are limited to particular aliphatic C1-C4 alcohols, a carbomer thickening agent, and an effective amount of a neutralizer that has been designated by the FDA as of February 5, 2002, as Generally Recognized As Safe or is an amino acid. Importantly, the present invention has a density of at least 0.8 g/ml and has a viscosity of from about 1000 to about 65,000 centipoise at 70 degrees Fahrenheit. This is important because, heretofore, it has been understood that certain neutralizers were not useful in high (*i.e.*, greater than 60%) alcohol compositions because they would not cause the thickener, namely a carbomer polymer, to gel the composition to a desired viscosity.

10. The same is true of the Samour et al. compositions. To support this known fact, I had two compositions prepared in a manner as set forth in the Samour et al. patent, by adding the ingredients in the listed in the Tables below. Each of these compositions were taken essentially directly from Example 5, Table 6, of

the Samour et al. patent (see Col. 12, lines 28-37), since it is believed that this Example most closely approximately the present invention with respect to the ingredients added, e.g., ethanol (SDA 3c), carbomer and sodium hydroxide. The sole difference between the two compositions is the addition of propylene glycol to the first composition. No penetration enhancer was used in either of these compositions since it is only available from the patentee and not obtainable. However, the lack of such an enhancer is believed to have no effect on the needed viscosity of the compositions. The compositions are set forth in Tables I and II below.

**Table I - Composition 1**

| Ingredient | Percent | Grams |
|---|---|---|
| Water | 10.5 | 5.25 |
| Propylene Glycol | 18 | 9 |
| Ibuprofen | 5 | 2.5 |
| Carbomer | 1 | 0.5 |
| SDA 3c | 65.5 | 32.75 |
| 25% w/w NaOH at pH 7.0 | | 2.24 |

Final pH =6.99

**Table II - Composition 2**

| Ingredient | Percent | Grams |
|---|---|---|
| Water | 28.5 | 14.25 |
| Propylene Glycol | 0 | 0 |
| Ibuprofen | 5 | 2.5 |
| Carbomer | 1 | 0.5 |
| SDA 3c | 65.5 | 32.75 |
| 25% w/w NaOH at pH 7.0 | | 2.17 |

Final pH =7.0

11. Both of these compositions were processed similarly. Addition of the first five ingredients resulted in a slightly hazy, colorless zero viscosity liquid. The sodium hydroxide was then added dropwise with stirring and continuous pH measurements taken until a pH of 7 was reached. Soon after beginning the

addition of the sodium hydroxide, *both compositions became heavily clouded and precipitation occurred.* Ultimately, both compositions resulted in a clear, colorless, *zero viscosity* solution with very heavy precipitation on the bottom of the container. The viscosity was below measurement and the pH was 7.0.

12. Thus, using the technology of the Samour et al. patent, it was not possible to construct a clear viscous alcohol gel with sodium hydroxide and 65% ethyl alcohol. As foreshadowed in the present application, there was precipitation and the viscosity was unmeasureable, i.e., zero. Thus, while the Samour et al. patent may have set forth each of the ingredients provided by the present invention individually of one another, it does not suggest using them together in a manner suitable for use as alcohol gel hand sanitizing composition, because, as previously noted, certain neutralizers such as sodium hydroxide have not heretofore been suitable for use in high (*i.e.*, greater than 60%) alcohol content compositions where carbomer polymer thickeners are used to gel the composition to a desired viscosity. This has been proven above.

13. With respect to McKenzie et al. U.S. Patent No. 5,747,021, I understand that the Examiner asserts that McKenzie et al. teach a transparent topical composition comprising isopropyl alcohol (30-70%), carbomer (0.25-1.75%), and sodium hydroxide (0.1%) that is available, according to the Examiner, as a gel, lotion, solution, cream, ointment, and so on. Accordingly, the Examiner asserts that all of the elements required by the claims of the present invention are taught by the reference and that the claimed subject matter is not considered to be patentably distinct over McKenzie et al.

14. Again, I respectfully disagree. First, McKenzie et al. teach an after shave composition comprising water, glycerin, propylene glycol, carbomer, alcohol of various types, acetylsalicylic acid and Peg-8. While the ingredients and, in this case, the order of addition of ingredients, are similar to the present invention, they are not identical. Moreover, as now amended, the claims of the present invention are limited to particular aliphatic C1-C4 alcohols, a carbomer thickening agent, and an effective amount of a neutralizer that has been designated by the FDA as of February 5, 2002, as Generally Recognized As Safe or is an amino acid. As previously noted, the present invention has a density of at least 0.8 g/ml and has a viscosity of from about 1000 to about 65,000 centipoise at 70 degrees Fahrenheit. Again, this is important because, heretofore, it has been understood that certain neutralizers were not useful in high (*i.e.*, greater than 60%) alcohol compositions because they would not cause

the thickener, namely a carbomer polymer, to gel the composition to a desired viscosity.

15. This is also true of the McKenzie et al. patent. To support this conclusion, I had a batch of the McKenzie composition prepared in a manner as set forth in the McKenzie et al. patent, by adding the ingredients in the amounts set forth in Table III below. Where possible, the formula was constructed as close to the present claims as possible, but remaining within the parameters, definitions, and intents of the McKenzie et al. patent. The batch essentially follows the Example set forth at Column 3 of the McKenzie et al. patent.

**Table III - Batch 1**

| | Ingredient | Percent | Grams |
|---|---|---|---|
| Phase 1 | Water | 17.9 | 53.7 |
| | Glycerin | 2 | 6 |
| | Propylene Glycol | 2 | 6 |
| | Carbomer | 1 | 3 |
| | NaOH, ACS 98.1% | 0.1 | 0.3 |
| | Isopropyl Alcohol | 35 | 105 |
| Phase 2 | Ethanol, SDA 40-1 | 30 | 90 |
| | Acetylsalicylic Acid | 8 | 24 |
| Phase 3 | Peg-8 | 4 | 12 |
| | Totals | 100 | 300 |

16. As noted, the batch was manufactured per the Example section of the McKenzie et al. patent. First, phase 1 ingredients were combined with the first three ingredients being added initially with vigorous mixing. Carbomer was then added and mixed vigorously until homogeneous. Next, sodium hydroxide was added. To this point, the batch had resulted in a very viscous, clear, colorless gel-form solution. Next, isopropyl alcohol was added at a rate of about 20 grams per minute (by pipette). Shortly thereafter, a white precipitate appeared, and the batch became completely opaque. Viscosity rapidly decreased.

17. Then, Phase 2 ingredients were prepared in a separate container and added to the Phase 1 ingredients. Next, Peg - 8 was added.

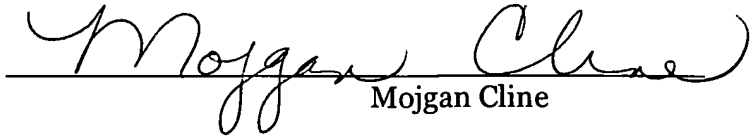
18. After two hours of rapid mixing the batch resulted in a heavily clouded, very slightly viscous liquid with some precipitation at the bottom of the container. The resulting viscosity was measured as 40 cps (rvt7, 100) and the resulting pH was 4.88. Thus, using the technology of the McKenzie et al. patent, it was not possible to construct a clear viscous alcohol gel with sodium hydroxide and 65% alcohol.

19. Next, with respect to Sequeira et al., I understand that the Examiner asserts that Sequeira et al. teach a topical composition comprising 20-50% propylene glycol, 20-40% isopropyl alcohol, 0.1-3% by weight of a thickener and sodium hydroxide to neutralize the carbomer thickener.

20. In light of the amendments made to the claims wherein the aliphatic alcohol is limited to at least 60 wt. % of a select group of low molecular weight alcohols, Sequeira et al. does not teach the present invention.

21. Notwithstanding this difference, it is further believed that the topical composition as taught by Sequeira et al. would not achieve the desired results of an alcoholic gel sanitizing composition for the same reasons as presented above for both Samour et al. and McKenzie et al. However, no specific testing of examples from this patent have been performed at this time, given the clear distinction made over this prior art with respect to the types of alcohol used.

I hereby declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Mojgan Cline

April 16, 2004